4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1048]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with medical device labeling regulations.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-1048 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations." Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Labeling Regulations

OMB Control No. 0910-0485--Revision

This information collection supports implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), codified in Agency regulations, and discussed in associated Agency guidance.

Medical device labeling requirements, among other things, provide for the label or labeling content of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 of the FD&C Act require that manufacturers, importers, and distributors of medical devices disclose information about themselves or the devices on the labels or labeling for the devices. Section 502 provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use. Medical device labeling regulations in parts 800, 801, 809, and associated regulations in part 1040 (21 CFR parts 800, 801, 809, and 1040), prescribe the disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves and/or the devices, on the label or labeling for the devices, to health professionals and consumers.

In conjunction with provisions in part 800, part 801, subpart A sets forth general labeling provisions applicable to all medical devices, including content and format requirements pertaining to intended uses, adequate directions for use, misleading statements, and the prominence of required labeling. Information collection provisions found in part 801, subpart B pertaining to labeling requirements for Unique Device Identification are currently approved under OMB control number 0910-0720 and not covered in this information collection request. Information collection associated with labeling requirements for Over-the-Counter (OTC) Devices are found in part 801, subpart C, and cover principal display panel; statement of identity; declaration of net quantity of contents; and certain warning statement elements. Information collection associated with exemptions from adequate directions for use and other exemptions are found in part 801, subparts D and E, respectively. Information collection associated with special labeling requirements applicable to specific devices are found in part 801, subpart H. We also include information collection associated with labeling for in vitro diagnostic products for human use, as set forth in part 809, subpart B. Finally, in addition to the

labeling requirements in part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, sunlamp products and ultraviolet lamps are subject to specific labeling requirements as set forth in part 1040.

We have revised the information collection to include reference to Agency guidance. The guidance documents were developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Section 502(b) of the FD&C Act requires that, for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may, however, grant an exemption if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case as it relates to protection of the public health. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add paragraph (u) to section 502 to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) amended section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA required that FDA

issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not "prominent and conspicuous" under section 502(u) of the FD&C Act. Accordingly, we issued the guidance document entitled "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended--Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" (May 2006), available at https://www.fda.gov/media/71187/download. The guidance document is intended to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act. We believe the information disclosures discussed in the guidance impose no burden beyond that which we attribute already to complying with disclosure provisions found in the applicable regulations; however, we include the guidance document for respondents' instructional use and reference.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Symbols glossary	3,000	1	3,000	1	3,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our figures are based on data from the FDA Unified Registration and Listing System and the OASIS shipment information. FDA allows the use of stand-alone graphical representations of information, or symbols, in the labeling for the medical devices, if the symbol has been established in a Standards Development Organization developed standard, provided that such symbol is explained in a symbols glossary that is included in the labeling for the medical device and otherwise complies with section 502 (misbranding) of the FD&C Act.

Table 2.--Estimated Annual Recordkeeping Burden[1,2]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Processing, labeling, or repacking agreement; 801.150	7,500	887	6,652,500	0.5 (30 minutes)	3,326,250
Impact resistant lenses; invoices, shipping documents, and records of sale or distribution; 801.410(e) and (f)	1,591	47,050	74,856,550	0.0008 (0.048 minutes)	59,885

Hearing aid records; 801.421	10,000	160	1,600,000	0.25 (15 minutes)	400,000
Menstrual tampons, sampling plan for measuring absorbency; 801.430(f)	33	11	363	80	29,040
Latex condoms; justification for the application of testing data to the variation of the tested product; 801.435(g)	51	3.65	186	1	186
Total			83,109,599		3,815,361

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

As set forth in § 801.150(a)(2) (21 CFR 801.150(a)(2)), device manufacturers are required to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the final shipment or delivery of the device. Section 801.150(a)(2) requires that copies of this agreement be made available for inspection at any reasonable hour upon request by any officer or employee of the Department of Health and Human Services (HHS). In § 801.410(e) (21 CFR 801.410(e)) copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, are required to be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee acting on behalf of the Secretary of HHS. Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years. Specific recordkeeping requirements applicable to hearing aid dispensers, manufacturers of menstrual tampons, and manufacturers of latex condoms are set forth in 21 CFR 801.421(d), 801.430(f), and 801.435(g), respectively.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1,2]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Parts 800; and Part 801, subparts A, C, D, and E: General Labeling; OTC Devices; Exemptions					
Contact lens cleaning solution labeling; 800.10(a)(3) and 800.12(c)	47	8	376	1	376
Liquid ophthalmic preparation labeling; 800.10(b)(2)	25	8	200	1	200
Manufacturer, packer, or distributor information; 801.1	19,407	7	135,849	1	135,849
Adequate directions for use; 801.5	8,526	6	51,156	22.35	1,143,337

Statement of identity; 801.61	8,526	6	51,156	1	51,156
Declaration of net quantity of contents; 801.62	8,526	6	51,156	1	51,156
Prescription device labeling; 801.109	9,681	6	58,086	17.77	1,032,188
Retail exemption for prescription devices; 801.110	30,000	667	20,010,000	0.25	5,002,500
Processing, labeling, or repacking; non-sterile devices; 801.150(e)	453	34	15,402	4	61,608
Part 801, subpart H: Special Requirements for Specific Devices					
Labeling of articles intended for lay use in the repairing and/or refitting of dentures; 801.405(b)(1)	35	1	35	4	140
Dentures; information regarding temporary and emergency use; 801.405(c)	35	1	35	4	140
Hearing aids professional and patient labeling; 801.420	136	12	1,632	80	130,560
Hearing aids, availability of User Instructional Brochure; 801.421	10,000	5	50,000	0.17	8,500
User labeling for menstrual tampons; 801.430	16	8	128	2	256
User labeling for latex condoms; 801.437	52	6	312	100	31,200
Part 809 (in vitro diagnostic products for human use) and Part 1040 (light-emitting products)					
Format and content of labeling for IVDs; 809.10	1,700	6	10,200	80	816,000
Advertising and promotional materials for ASRs; 809.30(d)	300	25	7,500	1	7,500
Labeling of sunlamp products--1040.20(d)	30	1	30	10	300
FD&C Action Section 502(u)					
Establishments listing < 10 SUDs	161	2	322	0.1 (6 minutes)	32
Establishments listing > 10 SUDs	14	45	630	0.1 (6 minutes)	63
Total			952		95

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Because many labeling provisions correspond to specific recordkeeping requirements, we have accounted for burden attendant to the provisions enumerated in table 3 as third-party disclosures. These figures reflect what we believe to be the average burden incurred by respondents to applicable information collection activities.

Overall, the information collection reflects changes and adjustments. For efficiency of operations, we have consolidated related information collection currently approved under OMB control numbers 0910-0577 and 0910-0740 pertaining to recommendations found in Agency guidance and discussed in this notice. This results in an increase to the information collection by

30,482 burden hours annually. At the same time, we have reduced our estimate of the total responses by 53,143,810 annually. Upon review, we believe we previously double-counted burden ascribed to disclosures provisions having accounted for the same burden as that associated with recordkeeping activities. We invite comment on our estimates and these assumptions.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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